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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/951,690	10/16/97	HERRICK	5488.1313/18

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QM31/0610

EXAMINER
NGUYEN, T

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/951,690Applicant(s)
HERRICKExaminer
Tram NguyenGroup Art Unit
3738☒ Responsive to communication(s) filed on Mar 15, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-38 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 21-28 is/are allowed.☒ Claim(s) 1-18, 20, 29, and 31-37 is/are rejected.☒ Claim(s) 19, 30, and 38 is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Drawings

1. The corrected or substitute drawings were received on March 13, 1999. These drawings are approved by the examiner. Pursuant to applicant's amendment of the same date, the examiner has withdrawn all prior objections to the drawings.

Specification

2. In response to applicant's amendment of March 13, 1999, the examiner has withdrawn all prior objections to the specification.

Claim Objections

3. The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 32-37 been renumbered 33-38.

4. Claims 33 and 38 are objected to because of the following informalities:

a. Claim 33 is grammatically awkward. The verb tenses appear to be inconsistent, and the claim reads as a fragment rather than a sentence.

b. In claim 38, line 2, "slop" should be --s lope --.

Appropriate correction is required.

5. In response to applicant's amendment of March 13, 1999, the examiner has withdrawn all prior objections to the specification.

Claim Rejections - 35 USC § 112

6. In response to applicant's amendment of March 13, 1999, the examiner has withdrawn all prior 35 U.S.C. § 112 rejections.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Guena et al. (U.S. Patent No. 5,417,651) for the following reasons:

With respect to claims 1-4, see Figures 1 and 4 for a punctum plug (10) comprising an elongated member (2) having a thin elongated lip (3) which is positioned in a generally anterior direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, the central axis being coaxial with the elongated axis of the elongated member, wherein one end is curved anteriorly relative to the thin elongated lip.

Depending upon the angle in which the implant is inserted, the elongated member positions the posterior surface away from a surface of an eye.

9. Claims 1-3, 5, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Seder et al. (U.S. Patent No. 4,959,048), for the following reason:

a. With respect to claims 1-3, see Figure 4 for a punctum plug (100) comprising an elongated member (106) having a thin elongated lip (104) which is positioned in a generally anterior direction upon insertion in to a punctum opening, the thin elongated lip having a posterior edge which is positioned away from the cornea, wherein one end is curved anteriorly relative to the thin elongated lip. Depending upon the angle and depth in which the implant is inserted, the elongated member positions the posterior surface away from a surface of an eye.

b. With respect to claim 5, see Figure 4 for a punctum plug (100) comprising an elongated member having at one end an external retaining member having a posterior surface (104), the elongated member having a portion curved anteriorly relative to the retaining member.

Depending upon the angle and depth in which the implant is inserted, the elongated member positions the posterior surface away from a surface of an eye.

c. With respect to claim 18, see Figure 4 wherein the other end of the punctum plug includes a shaped distal tip (108).

10. The indicated allowability of claim 20 is withdrawn in view of the newly discovered reference(s) to Tajiri et al. '777. Rejections based on the newly cited reference(s) follow.

11. Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Tajiri et al. (U.S. Patent No. 5,423,777) for the following reasons:

With respect to claim 20, see Figures 1 and 2 for a punctum plug (10) wherein the tip insertion section gently expands to a generally oval shape.

12. Claims 29, 31-33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Herrick (U.S. Patent No. 5,163,959), for the following reasons:

a. With respect to claims 29, 33, and 35-37, see Figure 1 and 10(b) for a punctum plug comprising an elongated member having a central member (22) with a predetermined cross-sectional dimension, the member having at one end a tip insertion section (26) having an offset (i.e., beveled or angled) distal starting tip (32), the offset distal starting tip having a smaller cross-section than the tip insert section, and wherein the member has a second end which comprises a thin elongated lip (34).

b. With respect to claims 31 and 32, see Figures 10(a) through 10(d) for the method of treating a tear deficiency with the recited punctum plug.

13. Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by MacKeen et al. (U.S. Patent No. 4,915,684), for the following reasons:

With respect to claims 33-37, see Figure 4 for a punctum plug having a starting tip (58) and an enlarged annular shaped section (46) at the end of a dilated punctal opening (50) having a

conical flared shape with a rounded outer edge, the starting tip having an external retaining member (60).

Double Patenting

14. The examiner notes in appreciation that applicant's amendment of March 13, 1999 indicated a terminal disclaimer had been submitted, with the appropriate fees, along with the amendment. However, the examiner has not received the terminal disclaimer at the time of the office action. Therefore, the examiner maintains the double patenting rejection of the previous office action, Paper No. 2. Upon receipt of a proper terminal disclaimer, the examiner will remove this double patenting rejection.

Response to Arguments

15. Applicant's arguments filed March 15, 1999 have been fully considered but they are not persuasive. Applicant is asked to please refer to the modified prior art rejection above wherein examiner addresses applicant's specific concerns regarding prior art rejections, as well as examiner's response below.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the lip extends or protrudes beyond the outer surface of the elongated member and is located around approximately 300 degrees or less of the periphery of the elongated member leaving the posterior free from protruding into, or from contacting with or abrading the surface of the eye including the

cornea or conjunctiva) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). That applicant has amended the claims to functionally recite that the lip is located on the elongated member of the punctum plug to position the posterior surface away from the surface of the eye is not sufficient to overcome the prior art, since such limitation could be met by the prior art, depending on how deep or how angled the punctum plug is inserted into the punctum opening of the eye. That is, if the punctum plug is partially inserted and not completely deployed, then such limitation is not relevant, since the lip will not even contact the surface of the eye.

The examiner also respectfully disagrees with applicant's specific arguments of Seder et al. Applicant argues that Seder et al. fails to show a shaped distal tip; clearly, in Figure 4 Seder et al. shows a shaped distal tip (108). Without further recitation of the specific shape of the distal tip, Seder et al. meets this limitation. Further, with respect to applicant's arguments of Herrick, the examiner asserts that the recitation of "an offset distal starting tip" does not in itself equate to a starting tip *which is not concentric* with the elongated axis. Broadly interpreted, the prior art meets this limitation.

Allowable Subject Matter

16. Claims 21-28 are allowed.

17. Claims 19, 30, and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion


18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No.'s 5,830,171 and 5,868,697 all show various features of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tram Nguyen whose telephone number is (703) 308-0804. The examiner can normally be reached on Monday - Friday from 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached at (703) 308-2672. The fax phone number for this group is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceedings should be directed to the group receptionist whose telephone number is (703) 308-0858.


TAN
June 4, 1999


Mickey Yu
Supervisory Patent Examiner
Group 3700